

NOV 24 2008

510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 C.F.R. §807.92.

1. The submitter of this premarket notification is:

Dr. Jens-Peter Seher
Philips Medizin Systeme Böblingen GmbH
Hewlett-Packard-Str. 2
D-71034 Böblingen, Germany

Tel: ++49 7031 463-2086 Fax: ++49 7031 463-2442
e-mail: jens-peter.seher@philips.com

This summary was prepared on October 29, 2008.

2. The name of the device is the Philips IntelliVue MP5 Patient Monitor with Microstream Side Stream CO₂ Measurement Module.

Classification names are as follows:

Device Panel	Classification	ProCode	Description
Cardiovascular Devices	§870.1025, II	DSI	Detector and alarm, arrhythmia
	§870.1025, II	MLD	Monitor, ST Segment with Alarm
	§870.1025, II	MHX	Monitor, Physiological, Patient (with arrhythmia detection or alarms)
	§870.1100, II	DSJ	Alarm, Blood Pressure
	§870.1110, II	DSK	Computer, Blood Pressure
	§870.1130, II	DXN	System, Measurement, Blood-Pressure, Non-Invasive
	§870.1435, II	DXG	Computer, Diagnostic, Pre-Programmed, Single-Function
	§870.2060, II	DRQ	Amplifier and Signal Conditioner, Transducer Signal
	§870.2300, II	DRT	Monitor, Cardiac (incl. Cardiachometer & Rate Alarm)
	§870.2340, II	DPS	Electrocardiograph
	§870.2340, II	MLC	Monitor, ST Segment
	§870.2350, II	DRW	Electrocardiograph, Lead Switching Adapter
	§870.2370, II	KRC	Tester, Electrode, Surface, Electrocardiograph
	§870.2450, II	DXJ	Display, Cathode-Ray Tube, Medical
	§870.2600, I	DRJ	System, Signal Isolation
	§870.2700, II	DQA	Oximeter
	§870.2770, II	DSB	Plethysmograph, Impedance
	§870.2800, II	DSH	Recorder, Magnetic tape, Medical
	§870.2810, I	DSF	Recorder, Paper Chart
	§870.2850, II	DRS	Extravascular Blood Pressure Transducer

Device Panel	Classification	ProCode	Description
	\$870.2900, I	DSA	Cable, Transducer and Electrode, incl. Patient Connector
	-	MSX	System, Network and Communication, Physiological Monitors
	\$870.2910, II	DRG	Transmitters and Receivers, Physiological Signal, Radiofrequency
Anesthesiology Devices	\$868.1400, II	CCK	Analyzer, Gas, Carbon Dioxide, Gaseous-Phase
	\$868.1500, II	CBQ	Analyzer, Gas, Enflurane, Gaseous-Phase (Anesthetic Concentration)
	\$868.1500, II	NHO	Analyzer, Gas, Desflurane, Gaseous-Phase (Anesthetic Concentration)
	\$868.1500, II	NHP	Analyzer, Gas, Sevoflurane, Gaseous-Phase (Anesthetic Concentration)
	\$868.1500, II	NHQ	Analyzer, Gas, Isoflurane, Gaseous-Phase (Anesthetic Concentration)
	\$868.1620, II	CBS	Analyzer, Gas, Halothane, Gaseous-Phase (Anesthetic Concentration)
	\$868.1700, II	CBR	Analyzer, Gas, Nitrous Oxide, Gaseous-Phase (Anesthetic Concentration)
	\$868.1720, II	CCL	Analyzer, Gas, Oxygen, Gaseous-Phase
	\$868.1880, II	BZC	Data calculator Pulmonary-function
	\$868.2375, II	BZQ	Monitor, Breathing Frequency
General Hospital and Personal Use Devices	\$880.2910, II	FLL	Thermometer, Electronic, Clinical

3. Indicated for use whenever there is a need for monitoring, transport monitoring, recording, and alarming of multiple physiological parameters of adult, pediatric and neonatal patients in a hospital environment and during transport inside and outside of hospital environment by health care professionals.
4. The modified device Philips IntelliVue MP5 Patient Monitor is substantially equivalent to the legally marketed IntelliVue MP5 Patient Monitor (K063725, K081793). The modification consists of the integration of the Microstream CO₂ Measurement Module, which is substantial equivalent to the legally marketed Philips M3015A Measurement Server Extension (k993383) and to the Oridion Capnostream₂₀ with A² Adaptive Averaging Software and Extended CO₂ Measurement Range (k072295).

5. The modification adds to the MP5 patient monitor the Microstream CO₂ Measurement Module as an integrated measurement module together with an extended CO₂ measurement range and an improved software algorithm for reduced generation of nuisance alarms (SARA).
6. The modified device has the same intended use as the legally marketed predicate device. The device is intended for monitoring, transport monitoring, recording, and alarming of multiple physiological parameters of adult, pediatric and neonatal patients in a hospital environment and during transport inside and outside of hospital environment by health care professionals.
7. The modification is the integration of the Microstream CO₂ measurement module into the MP5 with minor hardware and software adaptations. The modification leads to a compact patient monitor with integrated side stream CO₂ measurement and reduces manufacturing costs.
8. The accuracy of the device was validated according to ISO 21647.
9. Verification, validation, and testing activities establish the performance, functionality, and reliability characteristics of the modified device with respect to the predicate device. Testing involved system level tests, performance tests, and safety testing from hazard analysis. Pass/Fail criteria were based on the specifications cleared for the predicate device and test results showed substantial equivalence. The results demonstrate that the Philips IntelliVue MP5 Patient Monitor meets all reliability requirements and performance claims.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Philips Medizin Systeme Boblingen GMBH
Dr. Jens-Peter Seher
Senor Regulatory Affairs Engineer
Cardiac and Monitoring Systems
Hewlett-Packard -Str. 2
D-71034 Boblingen, Germany

Re: K083228

Trade/Device Name: Philips IntelliVue MP5 Patient Monitor

Regulation Number: 21 CFR 870.1025

Regulation Name: Arrhythmia Detector and Alarm (including ST-segment
measurement and alarm)

Regulatory Class: Class II (two)

Product Code: MHX

Dated: October 29, 2008

Received: November 3, 2008

Dear Dr. Seher:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

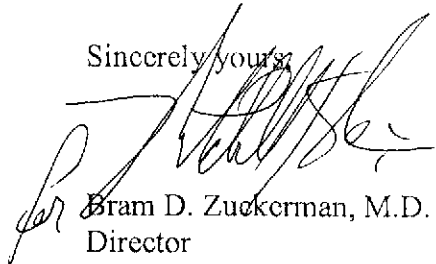
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any

Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman", is written over the typed name and title.

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K083228

Device Name: Philips IntelliVue MP5 Patient Monitor.

Indications for Use: Indicated for use whenever there is a need for monitoring, transport monitoring, recording, and alarming of multiple physiological parameters of adult, pediatric and neonatal patients in a hospital environment and during transport inside and outside of hospital environment by health care professionals.

Prescription Use yes AND/OR
(Part 21 CFR 801 Subpart D)

Over-The-Counter Use No
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)

Division of Cardiovascular Devices

510(k) Number K083228